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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/730,236

12/08/2003

Robert Sixto JR.

ISD-056 CI

2523

36822 7590 12/27/2007  
GORDON & JACOBSON, P.C.  
60 LONG RIDGE ROAD  
SUITE 407  
STAMFORD, CT 06902

EXAMINER

BLATT, ERIC D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

12/27/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/730,236

Applicant(s)

SIXTO ET AL.

Examiner

Eric Blatt

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 10-07-2004, 12-16-2005.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steckel (US 5,464,416) in view of Loeser (US 5,632,753).

Regarding claims 1-20, Steckel discloses a surgical clip comprising:

- a first arm portion 14 having a tip and an opposite end; said first arm portion comprises a catch portion 18;
- a second arm portion 12 substantially parallel to the first arm portion and having a first end and an opposite end;
- a retainer 22 extending from said first end of said second arm portion;
- said retainer 22 has a hook portion, and a tip portion that is capable of piercing tissue;
- a bridge portion 16 connecting said opposite ends of said first and second arm portions, wherein said first and second arm portions and said bridge portion are in a generally U-shaped configuration;

- said first and second arm portions and said bridge portion are substantially stiff;

Steckel does not disclose that the retainer extends substantially parallel to the first arm portion and is deformable to engage the catch portion of the second arm portion. Loeser discloses a surgical clip in which a first arm portion has a flexible retainer that extends parallel to the first arm portion and may be deformed 180 degrees to engage with a catch portion. This design allows the clip of Loeser to engage a wider variety of tissues and shapes. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Steckel by providing the retainer such that it extends substantially parallel to the second arm portion and may be deformed 180 degrees to engage the catch portion on the second arm portion in order to increase the versatility of the clip as taught by Loeser.

Regarding claims 3, 4, 14, and 15, the clip is a unitary piece. Steckel discloses that it was known to make clips from materials such as titanium, tantalum, and stainless steel. It would have been obvious to one of ordinary skill at the time of the invention to make the clip out of titanium, tantalum, or stainless steel since these materials were known in the art to be used for making clips.

Regarding claim 9, the modified clip has a first original configuration in which the retainer extends substantially parallel to both first and second arm portions and a second applied configuration in which the tip portion of the retainer is bent around or adjacent the tip of the first arm portion.

Regarding claim 16, Steckel does not specifically teach that the retainer portion have a length of .7 to 2 times the dimension between the outside legs of the clip. However, in the figures of Steckel the retainer portion (the hook) appears to fall within the range of .7 to 2 times the dimension of the outside legs of the clip. Also with no specific criticality or unexpected results shown in the specification for the length of the retainer, it would have been obvious for one of ordinary skill in the art to determine the optimum length of the retainer portion of a surgical clip for a specific application through routine experimentation.

Regarding claims 17-20, Steckel does not disclose a plurality of retainer portions. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a plurality of retainer portions on one or both arm portions. As taught by Loeser, these retainer portions extend longitudinally beyond the arm portions.

Regarding claims 21-26, Steckel discloses a method of applying a surgical clip to tissue, comprising:

- providing a surgical clip having, i) a first arm portion 14 having a tip and a first opposite end, ii) a second arm portion 12 having a retainer extending therefrom, and iii) a bridge portion 16 connecting the first and second opposite ends;
- providing the first and second arm portions about the tissue;
- folding the retainer about the tip of the first arm.
- providing a clip applier device

Steckel does not disclose that the retainer extends in substantially the same direction as the second arm. Loeser discloses a clip that has a retainer extending in substantially the same direction as the arm, so that the clip may be applied to tissue in front of the arm of the clip as well as beside it, by piercing the retainer through the tissue and plastically deformably bending said retainer substantially 180 degrees and folding the retainer about a catch portion. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Steckel by providing the retainer such that it extends in substantially the same direction as the second arm to increase the versatility of the device as taught by Loeser. Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method by piercing the retainer through a non-tubular tissue and plastically deformably bending the retainer substantially 180 degrees in order to apply the clip to a wider variety of tissues as taught by Loeser. Upon said modifications, the non-tubular tissue would be compressed by the clip applier device prior to the first and second arm portions being provided about the tissue. (See Figures 1, 3, and 5)

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Lingua; Robert W. (US 4519392): Hemostasing muscle clips for needleless surgery

- Oh; Seik et al. (US 5062846): Penetrating plastic ligating clip
- Chen; Chao C. et al. (US 5160339): Endoscopic suture clip
- Takahashi; Hiroshi et al. (US 5817116): Detaching tool for a tube for medical treatment
- Fogelberg; Mark et al. (US 5833700): Sterile occlusion fasteners and instrument and method for their placement
- Shank; Peter J. et al. (US 6231581): Implantable device anchors
- Schaller; Laurent et al. (US 6613059): Tissue connector apparatus and methods
- Ho; Liem et al. (US 6960221): Tissue connector apparatus with cable release
- Gallagher; Richard J. et al. (US 7001412): Surgical clip with integral suture-securing mechanism
- Peterson, James Arthur et al. (US 2002/0111641): Bioabsorbable surgical clip with engageable expansion structure

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is 571-272-9735.

The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric Blatt  
571-272-9735



MICHAEL J. HAYES  
SUPERVISORY PATENT EXAMINER

Eric Blatt  
571-272-9735